

Application Serial No.: 09/914,605

REMARKS

I. Status Summary

Claims 106-184 are pending in the subject U.S. patent application and have been examined. An Official Action (hereinafter the "Official Action") was issued April 18, 2005 by the United States Patent and Trademark Office (hereinafter the "Patent Office").

Claims 112, 151, 157, 170, 172, and 173 presently stand objected to as being dependent upon a rejected base claim. According to the Patent Office, these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 106-111, 113-126, 132-144, 146-150, 152-156, 158-169, 171, and 174-184 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0157025 to Unger et al. (hereinafter "Unger et al.").

Claims 106-108, 113-137, 142-147, and 152 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 107, 113, 122, 138, 152, 153, 158-172, and 174-184 have been cancelled in the instant amendment. Applicants respectfully reserve the right to file one or more continuation applications directed to the subject matter of the cancelled claims.

Claims 106, 109, 112, 114, 115, 123, 125-128, 132, 135, 139, 140, 142-145, 148, 151, 155-157, and 173 have been amended. Support for the amendments can be found throughout the specification as filed, including particularly in the claims as filed.

Reconsideration of the application as amended and based on the remarks set forth herein below is respectfully requested.

II. Responses to the Objections to the Claims

Claims 112, 151, 157, 170, 172, and 173 have been objected to as being dependent upon a rejected base claim. The Patent Office indicates that the claims

Application Serial No.: 09/914,605

would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Initially, applicants submit that claims 170 and 172 have been cancelled in the instant amendment. As such, the objection to these claims has been rendered moot. Applicants respectfully reserve the right to file one or more continuation applications with claims directed to the subject matter of the cancelled claims.

Applicants respectfully submit that independent claim 106 as currently amended addresses the instant objection. Applicants submit that claim 106 has been amended to overcome the 35 U.S.C. § 102(e) and 35 U.S.C. § 112 rejections, as discussed in more detail below. Applicants further submit that claims 112 and 157 depend either directly or indirectly from independent claim 106. Accordingly, applicants respectfully submit that claims 112 and 157 are now in condition for allowance, and respectfully solicit a Notice of Allowance at this time.

Applicants further submit that claims 151 and 173 have been amended to independent form. Accordingly, applicants respectfully submit that claims 151 and 173 are now in condition for allowance, and respectfully solicit a Notice of Allowance at this time.

III. Response to the Rejection under 35 U.S.C. § 102(e)

Claims 106-111, 113-126, 132-144, 146-150, 152-156, 158-169, 171, and 174-184 presently stand rejected under 35 U.S.C. § 102(e) upon the Patent Office assertion that the claims are anticipated by Unger et al.

The Patent Office asserts that Unger et al. teach that the gamma subunit of fibrinogen may be used as the targeting ligand in the disclosed invention. Further, the Patent Office asserts that Unger et al. teach that the bioactive agent of the invention may be a drug or a diagnostic agent. Additionally, the Patent Office contends that Unger et al. teach that the diagnostic agent may be a magnetic resonance imaging agent, and that a lipid vesicle may be employed. Finally, the Patent Office asserts that Unger et al. teach that the radioisotopes ⁹⁹Tc and ¹¹¹In

Application Serial No.: 09/914,605

may be used as imaging agents and thus would inherently meet the limitations as therapeutic toxins, depending on the manner of use (i.e., dosage).

After careful consideration of the rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants submit that claims 107, 113, 122, 138, 152, 153, 158-169, 171, and 174-184 have been cancelled in the instant amendment. As such, rejection of these claims is considered moot. Applicants respectfully reserve the right to file one or more continuation applications with claims directed to the subject matter of the cancelled claims.

Further, "[a] claim is anticipated only if each and every element in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaa| Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that claim 106 has been amended to recite a delivery vehicle for use in targeted delivery of an active agent, the delivery vehicle comprising (1) a targeting agent that preferentially binds a radiation inducible target selected from the group consisting of ICAM-1, P-selectin, β_3 Integrin, an activated platelet and combinations thereof in a target tissue, (2) a pharmaceutically acceptable diluent or excipient; and (3) an active agent comprising a toxin, a radiosensitizing agent, or combinations thereof.

Initially, applicants respectfully submit that Unger et al. does not teach delivery vehicles comprising an active agent comprising at least one toxin, as recited in amended independent claim 106 of the instant application. The Patent Office asserts that paragraph [360] of Unger et al. teaches ^{99}Tc and ^{111}In radioisotopes used as imaging agents and that such radioisotopes would inherently meet the limitations of the disclosed subject matter as therapeutic toxins, depending on the manner of use. In response, applicants respectfully submit that paragraph [360] of Unger et al. recites the use of ^{99}Tc and ^{111}In radioisotopes for imaging and screening using NMI and ultrasound methods to rapidly localize regions of vesicle uptake *in vivo*.

Application Serial No.: 09/914,605

Unger et al. recites at paragraph [360]: "In this case, high energy, high quality nuclear medicine imaging isotopes, such as technetium^{99m} or indium¹¹¹ can be incorporated in the wall of vesicles. Whole body gamma scanning cameras can then be employed to rapidly localize regions of vesicle uptake in vivo." Therefore, applicants respectfully submit that the use of the radioisotopes recited in Unger et al. is limited to imaging analysis. Applicants further submit that there is no support in the reference for the use of such radioisotopes as therapeutic toxins.

Applicants respectfully submit that one of skill in the art would not use a toxic compound for imaging, as this would cause more harm than good. Further, applicants submit that the specification at page 7 defines the term "toxin" as compounds that, when contacted with and/or incorporated into a cell, produce the death of the cell. Thus, applicants respectfully submit that the disclosure of Unger et al. does not include a "toxin."

Therefore, applicants submit that it is axiomatic that to support a rejection under 35 U.S.C. § 102(e), the Patent Office must consider the reference in its entirety. Applicants respectfully submit that when Unger et al. is considered in its entirety, it is clear that the reference does not disclose a delivery vehicle comprising a toxin, as recited in claim 106 of the instant application. Accordingly, applicants respectfully submit that Unger et al. does not support the instant rejection of claim 106.

Continuing with the instant rejection, applicants further respectfully submit that Unger et al. does not disclose the use of a delivery vehicle comprising an active agent comprising at least one radiosensitizing agent, as recited in claim 106 of the instant application. Thus, for this additional reason, applicants respectfully submit that Unger et al. does not support the instant rejection of claim 106.

Summarily, applicants respectfully submit that Unger et al. does not teach each and every element of claim 106, and as such, applicants respectfully submit that the instant rejection of claim 106 under 35 U.S.C. § 102(e) based on Unger et al. is improper. Furthermore, claims 108-111, 114-121, 123-126, 132-137, 139-144,

Application Serial No.: 09/914,605

146-150, and 154-156, depend directly or indirectly from claim 106, and thus are also believed to have been distinguished from Unger et al.

Accordingly, applicants respectfully request that the rejection of claims 106, 108-111, 114-121, 123-126, 132-137, 139-144, 146-150, and 154-156 under 35 U.S.C. § 102(e) be withdrawn at this time. Applicants further respectfully submit claims 106, 108-111, 114-121, 123-126, 132-137, 139-144, 146-150, and 154-156 are in condition for allowance and respectfully solicit a Notice of Allowance to that effect.

IV. Response to the Rejection under 35 U.S.C. § 112

Claims 106-108, 113-137, 139-147, and 152 stand rejected under 35 U.S.C. § 112, first paragraph, upon the Patent Office contention that the claims fail to comply with the written description requirement. The Patent Office asserts that structures of the targeting agents are not known (other than ICAM-1, P-selectin, β_3 integrin, and activated platelets), nor does the art teach ways to determine the structure of other targeting agents.

After careful consideration of the rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants submit that claims 107, 113, 122, and 152 have been cancelled in the instant amendment. As such, the rejection of these claims has been rendered moot. Applicants respectfully reserve the right to file one or more continuation applications with claims directed to the subject matter of the cancelled claims.

As conceded by the Patent Office, the cell adhesion molecules ICAM-1, P-selectin, and β_3 integrin, and activated platelets are disclosed in the instant specification as radiation inducible targets and as such satisfy the written description requirement. Applicants respectfully submit that independent claim 106 has been amended to recite, *inter alia*, that the delivery vehicle comprises a targeting agent

Application Serial No.: 09/914,605

that preferentially binds a radiation inducible target selected from the group consisting of ICAM-1, P-selectin, β_3 Integrin, an activated platelet, and combinations thereof. Therefore, applicants respectfully submit that the rejection of claim 106 under 35 U.S.C. § 112, first paragraph, has been overcome.

Claims 108, 114-121, 123-137, and 139-147 depend directly or indirectly from independent claim 106. Applicants respectfully submit that in view of this dependency the instant rejection of claims 108, 114-121, 123-137, and 139-147 under 35 U.S.C. § 112, first paragraph, has been addressed, and that the claims are in condition for allowance. A Notice of Allowance to this effect is respectfully requested at this time.

CONCLUSIONS

In light of the above Amendments and the Remarks presented hereinabove, it is respectfully submitted that claims 106, 108-112, 114-121, 123-137, 139-151, 154-157, and 173 are in proper condition for allowance, and such action is earnestly solicited.

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

Application Serial No.: 09/914,605

Deposit Account

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date:

10/11/2005

By:

Arles A. Taylor, Jr.

Arles A. Taylor, Jr.
Registration No. 39,395

1242/21 PCT/US AAT/AD/ acy

Customer No: 25297